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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,593	06/07/2001	Benoit Van Den Eynde	L0461/7099	9143

7590 06/14/2004  
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EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/674,593

**Applicant(s)**

EYNDE ET AL.

**Examiner**

MISOOK YU, Ph.D.

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,8,9,12,13,25,66,67,71-76,80 and 81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/31/04</u> .   | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A</u> .            |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/2004 has been entered.

Claims 1, and 8 are amended. Claims 1, 2, 8, 9, 12, 13, 25, 66, 67, and 71-76, 80, and 81 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejections.

### ***Claim Rejections - 35 USC § 112, Withdrawn***

The rejection of claim 1 2, 12, 13, 66, 67, and 73 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because the amended claims do not have the limitations previously rejected.

Claims 1 2, 12, 13, 66, 67, and 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is also

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withdrawn because the amended claims have different limitations than the limitation rejected previously.

***Claim Rejections - 35 USC § 102, Maintained***

Claims 8, 9, 71, and 72 remain rejected for reason of record under 35 U.S.C. 102(b) as being anticipated by US Pat. 5,582,979 (Dec. 10, 1996).

Claims 8, 9, 71, and 72 are interpreted as drawn to nucleic acid molecules **comprising** a fragment of SEQ ID NO:1 or comprising complement to said fragment, with minimum 12 nucleotides in claim 8, and 14 nucleotides in claim 9, 5 nucleotides in claim 72. Claim 8 does not recite any transitional phrases. However, based on the transitional phrase “comprising” in the dependent claims 9, 71, and 72, scope of claim 8 includes polynucleotide comprising a fragment of fragment of SEQ ID NO:1, wherein the fragment does not contains nucleotide consisting of SEQ ID NO:10.

Applicant argues claim 8 has been amended to clarify that the claimed nucleic acid molecules consists of the recited fragments. However, the limitation “consisting of” in line 2 of claim 8 along with “or” is an alternative expression commonly referred to as a Markush group. Therefore, the limitation “consisting” refers that species (a) and (b) in claim 8 are the members of the Markush expression. Note MPEP 2173.05(h) for Markush group language.

Claim 8 is missing the transitional phrases, which define the scope of a claim with respect to what unrecited additional components, if any, are excluded from the scope of claim. However, the dependent claim 9 (see line 3), for example, recites

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“comprising”, which is inclusive or open-ended and does not exclude additional unrecited sequences. Note MPEP 2111.03 for the transitional phrases.

As stated in the two previous Office actions, US Pat. 5,582,979, teaches a nucleic acid molecule comprising 23 contiguous nucleotides that match nucleotides 1227 to 1249 of the instant SEQ ID NO:1. Note previously provided sequence alignment. Since instant SEQ ID NO:10 matches nucleotides 268 to 513 of the instant SEQ ID NO:1 (note the attached Exhibit A), the sequence disclosed in '979 patent meets that the limitation of claims 8, 9, 71, and 72.

Claims 8, 9, 71, and 72 remain rejected for reason of record under 35 U.S.C. 102(e) as being anticipated by US Pat. 6,087,485 (filing date: Jan. 21, 1998).

The reason for maintaining this rejection is same as the reason given above. See the rejection under 35 U.S.C. 102(b).

***The Following Are New Grounds of Rejection***

***Allowable Subject Matter***

The indicated allowability of claim 25, 74-76 is withdrawn in view of the new rejection below.

***Claim Rejections - 35 USC § 112***

Claims 1, 2, 8, 9, 12, 13, 66, 67, and 71-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The newly amended base claim 1 recites “a polypeptide encoded by a RUR-1 antisense mRNA”, but it is not clear what the metes and bounds are. The specification at page 11 under the heading Brief Description of the Sequences say that SEQ ID NO:5 is the amino acid of the polypeptide encoded by the **RUR-1 cDNA** and SEQ ID NO:2 is the amino acid of the polypeptide encoded by the **RUR-1 antisense cDNA**. The specification at page 28 lines 14 and 15 says “RUR-1 sense-encoded or RUR-1 antisense-encoded polypeptides”. It is not clear which polypeptide is “a polypeptide encoded by a RUR-1 antisense mRNA” based on the disclosure of the originally filed specification. Reciting a SEQ ID NO corresponding to “a polypeptide encoded by a RUR-1 antisense mRNA” would obviate this rejection. The specification originally filed does not define “a polypeptide encoded by a RUR-1 antisense mRNA”. Merriam-Wester Online Dictionary downloaded On 6/5/04 from [url>>>www.m-w.com](http://www.m-w.com) discloses the ordinary meaning of antisense is a complementary sequence to a segment of genetic material and serves to inhibit gene function. Therefore, antisense mRNA does not encode any protein.

Applicant states that the claim is amended to correspond to the language of the specification noted by the Examiner on page of the Office action. However, the supported terminologies noted by the Examiner in the last Office action is the bold-faced terminologies above, which is different form “RUR-1 antisense mRNA”.

Any claims depend from the rejected base claim 1 is also rejected for the same reason given above.

Claim 8 is missing a transitional phrase, which define the scope of a claim with respect to what unrecited additional components, if any, are excluded from the scope of claim. It is not clear the property boundary of claim 8 for patent protection based on applicant's argument traversing 102 art rejection above. Applicant argues at page 6 of the amendment that claim 8 is amended to clarify that claimed nucleic acid molecule consist of the recited fragments. However, the dependent claims, for example, claim 9 uses the transitional phrases "comprising", therefore, the scope of claim 8 could be interpreted as nucleic acid molecules comprising. However, applicant argues otherwise.

This rejection would be obviated if claim 8 is amended to include "wherein said nucleic acid molecule is selected from the group consisting of" after the limitation "consisting of" in line 2 and amend "or" in line 4 back to "and" so that it could be in a proper Markush format; this will make the "consisting of" in line 2 of claim 8 a transitional phrase and the "wherein..." suggested by the Office is a Markush language. Note MPEP 2173.05.

Claims 9, and 71 are drawn to nucleic acid molecule with minimum size of 12. However, the limitation "comprising" is used to, therefore, it broadens the claim 8 if the scope of claim 8 is limited to nucleic acid consisting of 12 contiguous SEQ ID NO:1 as applicant argues for traversing art rejection above.

As for claim 72, which depends from claim 8, the minimum length required in order to be the property boundary is 5 contiguous nucleotides, thus broadening the property boundary set by the base claim 8.

Claims 1, 2, 12, 13, 66, 67, and 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection due to the new limitation "a polypeptide encoded by a RUR-1 antisense mRNA" in the base claim 1. Applicant argues this language corresponds to the language of the specification noted by the Examiner on page 2 of the Office action. However, the Office action applicant referring to is as follows:

The specification at page 11 under the heading Brief Description of the Sequences say that SEQ ID NO:5 is the amino acid of the polypeptide encoded by the RUR-1 cDNA. SEQ ID NO:2 is the amino acid of the polypeptide encoded by **the RUR-1 antisense cDNA**. The specification at page 28 lines 14 and 15 says "RUR-1 sense-encoded or RUR-1 antisense-encoded polypeptides". However, the specification as originally filed does not describe "a RUR-1 encoded polypeptide". Applicant is requested to point out the support for the limitation in the originally filed specification. This rejection affects all dependent claims.

The specification as originally filed does not have support for "a polypeptide encoded by a RUR-1 antisense mRNA".



Claims 25, and 74-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection the presence of the expression of SEQ ID NO:2, does not reasonably provide enablement for any other tumor associated polypeptide precursor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the claimed invention is drawn to a kit containing a set of primers from SEQ ID NO:1 for detection of a tumor associated polypeptide precursor.

Van den Eynde et al (a copy provided in the previous Office action mailed on 06/18/2002, J. Exp. Med. 1999, Vol. 190, pages 1793-1799) at the paragraph bridging left and right columns of page 1796, Table 1 at page 1797, teach that RU2AS is expressed in a large number of tumor cells. Thus, the claimed primers could be able to detect the expression of the transcript, which encodes SEQ ID NO:2, although the said primers could detect expression of RU2S as shown at Figure 6. However, Van den Eynde et al teach that RU2S is a house keeping gene (note line 6 of the paragraph

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bridging left and right columns page 1796), not a tumor associated polypeptide precursor since not expressed in tumor. The specification does not teach which other tumor associated polypeptide precursor(s) could be detected with the claimed primers. Limiting the scope to a kit for detecting the expression of the transcript, which encodes SEQ ID NO:2 would obviate this rejection.

Considering the unpredictable state of art, limited guidance, no examples in the specification how to use the instantly claimed invention, broad breath of the claims, it is concluded that undue experimentation is required to practice the invention. It is noted that law requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina C Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.  
Examiner  
Art Unit 1642



LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER